

## REMARKS

Claims 1 – 95 are pending.

Claims 1 – 27 have been rejected.

Claims 28 – 95 are new.

### Amendments to the Claims

#### Claims 48 – 51, 57 – 65 and 72 – 78

Claims 48 – 51 are new, and are derived from the subject matter of claims 1 – 8. Claims 57 – 65 are new, and are derived from the subject matter of claims 9 – 20. Claims 72 – 78 are new, and are derived from the subject matter of claims 21 – 27. Support for these new claims may be found in the claims from which they derive and throughout the specification. No new matter has been added.

#### Claims 85 – 88

Claims 85 – 88 are new and are derived from the subject matter of claims 1 – 8 and 48 – 51. Claims 85 – 88 recite a transducer in place of an ultrasound emitting member. New claims 85 – 88 are supported in Figure 1, at page 16, lines 2 – 17 and throughout the specification. No new matter has been added.

#### Claims 28 – 47, 52 – 57, 66 – 71, 79 – 84 and 89 – 95

Claims 28 – 34 are new and depend from claim 1. Claims 35 – 40 are new and depend from claim 9. Claims 41 – 47 are new and depend from claim 21. Claims 52 – 57 are new and depend from new claim 48. Claims 66 – 71 are new and depend from new claim 58. Claims 79 – 84 are new and depend from new claim 72. Claims 89 – 95 are new and depend from new claim 85. Each of these groups of claims recites related subject matter that will be addressed below for each claim to which the subject matter pertains.

Claims 28, 35, 41, 52, 66, 79 and 89 recite an active surface or a transducer that is flexible in order to conform to a surface of the tissue of the patient. Support for this subject matter may be found at page 16, lines 15 – 17, of the specification. No new matter has been added.

Claims 29 and 42 recite that the handle is malleable. Support for this subject matter may be found in original claim 17 and throughout the specification. No new matter has been added.

Claims 30, 36, 43, 53, 67, 80 and 90 recite that the plurality of ultrasound emitting elements are arranged in an annular array. Support for this subject matter may be found at page 20, lines 16 – 17, of the specification. No new matter has been added.

Claims 31, 37, 44, 54, 68, 81 and 91 recite that the plurality of ultrasound emitting elements are arranged in a linear array. Support for this subject matter may be found at page 20, lines 16 – 17, of the specification. No new matter has been added.

Claims 32, 38, 45, 55, 69, 82 and 92 recite that the plurality of ultrasound emitting elements are arranged in a curved linear array. Support for this subject matter may be found at page 20, lines 16 – 17, of the specification. No new matter has been added.

Claims 33, 39, 46, 56, 70, 83 and 93 recite that the ultrasound emitting elements emit ultrasound energy at a frequency, and that the frequency is selectively variable. Support for this subject matter may be found at page 20, line 22, to page 21, line 1. No new matter has been added.

Claims 34, 40, 47, 57, 71, 84 and 94 recite a power supply that is removably coupled to the plurality of ultrasound emitting elements. Support for this subject matter may be found at page 18, lines 22 – 23. No new matter has been added.

Claim 95 recites that the transducer is flexible and that the plurality of ultrasound emitting elements are arranged in a curved linear array. Support for this subject matter has already been established with respect to claims 89 and 92. No new matter has been added.

## **Double Patenting Rejections**

### Hissong et al ‘531

Claims 1, 5, 6, 9 and 17 have been rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 8, 9 and 15 of U.S. Patent No. 6,361,531, Hissong et al. (“Hissong et al ‘531”). These rejections are respectfully traversed.

Claims 1 and 9 recite, among other subject matter, a plurality of ultrasound emitting elements being independently actuatable to emit ultrasound energy, and a controller that independently actuates the ultrasound emitting elements to create a lesion in accordance with the ultrasound emitting elements selected to be actuated. None of claims 1, 8, 9 or 15 of Hissong et al '531, or any other claim of Hissong et al '531 recites ultrasound emitting elements that are independently actuatable. Thus, the subject matter of claims 1 and 9 are patentably distinct from claims 1, 8, 9 and 15 of Hissong et al '531 because claims 1 and 9 each recite an essential element not found in the claims of Hissong et al '531. Claims 5 and 6 depend from claim 1 and claim 17 depends from claim 9, and as such incorporate all of the subject matter of the claims from which they depend. Thus, it is respectfully submitted that the rejections of claims 1, 5, 6, 9 and 17 on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 8, 9 and 15 of Hissong et al '531 are improper and should be withdrawn.

#### Hissong et al '720

Claims 21 and 24 – 26 have been rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 9, 10, 12, 17, 18, 19 and 20 of U.S. Patent No. 6,409,720, Hissong et al. ("Hissong et al '720"). While respectfully disagreeing that the rejections on the ground of nonstatutory obviousness-type double patenting are proper, nevertheless in order to expedite the prosecution of the above-identified application, a terminal disclaimer having been filed over Hissong et al '720, it is respectfully submitted that these rejections have been rendered moot and should be withdrawn.

#### Hissong et al '254

Claims 21 - 24 have been rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 5, 10, 11, 19, 28, 38 and 39 of U.S. Patent No. 6,413,254, Hissong et al. ("Hissong et al '254"). While respectfully disagreeing that the rejections on the ground of nonstatutory obviousness-type double patenting are proper, nevertheless in order to expedite the prosecution of the above-identified application, a terminal disclaimer having been filed over Hissong et al '254, it is respectfully submitted that these rejections have been rendered moot and should be withdrawn.

#### Bays et al '013

Claims 21 and 24 have been rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 9 – 11 and 17 – 23 of U.S. Patent No. 6,451,013, Bays et al. (“Bays et al '013”). While respectfully disagreeing that the rejections on the ground of nonstatutory obviousness-type double patenting are proper, nevertheless in order to expedite the prosecution of the above-identified application, a terminal disclaimer having been filed over Bays et al '013, it is respectfully submitted that these rejections have been rendered moot and should be withdrawn.

#### Hissong et al '934

Claims 21, 24 and 25 have been rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 8 – 10, 15 and 16 of U.S. Patent No. 6,595,934, Hissong et al. (“Hissong et al '934”). While respectfully disagreeing that the rejections on the ground of nonstatutory obviousness-type double patenting are proper, nevertheless in order to expedite the prosecution of the above-identified application, a terminal disclaimer having been filed over Hissong et al '934, it is respectfully submitted that these rejections have been rendered moot and should be withdrawn.

#### Hissong et al '046

Claims 21, 24 and 25 have been rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4 – 6, 10, 13 – 15, 19 and 22 – 24 of U.S. Patent No. 6,936,046, Hissong et al. (“Hissong et al '046”). While respectfully disagreeing that the rejections on the ground of nonstatutory obviousness-type double patenting are proper, nevertheless in order to expedite the prosecution of the above-identified application, a terminal disclaimer having been filed over Hissong et al '046, it is respectfully submitted that these rejections have been rendered moot and should be withdrawn.

### **Rejections Under 35 U.S.C. § 103**

#### Claims 1, 2, 4, 6, 9 – 12, 14, 16, 18 and 21 - 27

Claims 1, 2, 4, 6, 9 – 12, 14, 16, 18 and 21 – 27, have been rejected under 35 USC § 103(a) as being unpatentable over U.S. Patent No. 6,508,774 (“Acker et al ‘774”). These rejections are respectfully traversed.

Acker et al ‘774 was filed on March 9, 2000. It has a related provisional application, No. 60/123,505 (“Acker et al ‘505”), filed on March 9, 1999, from which Acker et al ‘774 claims priority. The present application is a continuation of U.S. Patent Application No. 09/487,710, filed January 19, 2000. Thus, only the disclosure of Acker et al ‘505 is a valid reference against the present application.

Acker et al ‘505 discloses a HIFU application with feedback control using bubble detection. The disclosure of Acker et al ‘505 is limited to stating that “it should be possible” to detect of cavitation and limit application of HIFU until echogenisity returns to the HIFU target area (page 1, lines 15 – 19). Different possible methods are disclosed. But Acker et al ‘505 does not show, disclose or suggest selectively, independently actuatable ultrasound emitting elements, as is recited in claims 1 and 21. Thus, claims 1 and 21 are patentable over Acker et al ‘505.

It is noted that Acker et al ‘505 incorporates by reference International Publication WO98/52,465. However, under 37 C.F.R. 1.57(c), “Essential material” may be incorporated by reference in a patent application, “only by way of an incorporation by reference to a U.S. patent or U.S. patent application publication ...” (emphasis added). “Essential material” is defined in 37 C.F.R. 1.57(c)(1) as material necessary to meet the written description, enablement and best mode requirements of 35 U.S.C. § 112, first paragraph, in 1.57(c)(2) as material necessary to meet the requirements of 35 U.S.C. § 112, second paragraph, and in 1.57(c)(3) as material necessary to meet the requirements of 35 U.S.C. § 112, sixth paragraph. The disclosure of Acker et al ‘505 meets none of these requirements, as it discloses only that “it should be possible” (page 1, line 15) to detect cavitation and limit application of HIFU until the cavitation has dissipated. The disclosure in International Application WO98/465 is ineligible for inclusion by incorporation by reference in Acker et al ‘505 since it would be “essential information” to meet the written description, enablement and best mode requirements of 35 U.S.C. § 112. Thus, Acker et al ‘505 must stand on its own explicit disclosure. Acker et al ‘505 does not show, disclose or suggest ultrasound emitting elements that are selectively, independently actuatable. Acker et al ‘774 is

not a valid reference against the present application, as the filing date of Acker et al '774, March 9, 2000, is later than the priority date of the present application, January 19, 2000.

Thus, it is respectfully submitted that the rejection of claims 1, 2, 4, 6, 9 – 12, 14, 16, 18 and 21 – 27 under 35 USC § 103(a) as being unpatentable over Acker et al '774 is improper and should be withdrawn.

#### Claims 5, 13 and 17

Claims 5, 13 and 17 have been rejected under 35 USC § 103(a) as being unpatentable over U.S. Patent No. 6,508,774 ("Acker et al '774") in view of U.S. Patent No. 6,626,855 ("Weng et al '855"). These rejections are respectfully traversed.

The discussion of Acker et al '774 above is incorporated in its entirety. It is noted that Acker et al '774 is not a valid reference against the present application.

Weng et al '855 discloses controlled high efficiency lesion formation using high intensity ultrasound. Weng et al '855 discloses that a single transducer or transducer array is utilized at any given time (e.g., column 8, lines 1 – 10). The transducer may be changed out depending on the type of lesion that is desired to be created (column 7, lines 45 – 55). Wider lesions may be formed by creating lesion columns where the transducer is "quickly shifted laterally to generate the next adjacent column" (column 7, lines 55 – 59). But Weng et al '855 does not show, disclose or suggest a plurality of ultrasound emitting elements, independently actuatable, whereby the ultrasound energy is focused at separate and distinct locations for each individual element, and whereby a lesion is formed in accordance with the elements that are selected to be actuated.

By contrast, claims 1 and 9, as amended, from which claims 5, 13 and 17 depend, recite a plurality of ultrasound emitting elements, independently actuatable, whereby the ultrasound energy is focused at separate and distinct locations for each individual element, and whereby a lesion is formed in accordance with the elements that are selected to be actuated. The disclosure of Weng et al '855, which discloses only one transducer and moving the transducer from place to place to generate adjacent lesion columns is the antithesis of the subject matter of claims 1 and 9, as amended.

Thus, Weng et al '855 does not show, disclose or suggest multiple essential elements of independent claims 1 and 9, as amended. Claim 5 depends from claim 1, and claims 13 and 17 depend from claim 9, and as such incorporate all of the subject matter of the claims from which they depend. In addition, claims 5, 13 and 17 recite additional patentable subject matter. Thus, the rejections of claims 5, 13 and 17 under 35 USC § 103(a) as being unpatentable over Acker et al '774 in view of Weng et al '855 are improper and should be withdrawn.

#### Claims 7, 8, 19 and 20

Claims 7, 8, 19 and 20 have been rejected under 35 USC § 103(a) as being unpatentable over U.S. Patent No. 6,508,774 ("Acker et al '774") in view of U.S. Patent No. 5,413,550 ("Castel '550"). These rejections are respectfully traversed.

The discussion of Acker et al '774 above is incorporated in its entirety. It is noted that Acker et al '774 is not a valid reference against the present application.

Castel '550 discloses an ultrasound therapy system with automatic dose control. Castel '550 discloses an ultrasonic transducer element 15 (Figure 2). The transducer element has an effective radiating area (column 6, line 11). But Castel '550 does not show, disclose or suggest a plurality of ultrasound emitting elements, independently actuatable, whereby the ultrasound energy is focused at separate and distinct locations for each individual element, and whereby a lesion is formed in accordance with the elements that are selected to be actuated.

By contrast, claims 1 and 9, as amended, from which claims 7, 8 19 and 20 depend, recite a plurality of ultrasound emitting elements, independently actuatable, whereby the ultrasound energy is focused at separate and distinct locations for each individual element, and whereby a lesion is formed in accordance with the elements that are selected to be actuated. Thus, Castel '550 does not show, disclose or suggest multiple essential elements of independent claims 1 and 9, as amended. Claims 7 and 8 depend from claim 1, and claims 19 and 20 depend from claim 9, and as such incorporate all of the subject matter of the claims from which they depend. In addition, claims 7, 8, 19 and 20 recite additional patentable subject matter. Thus, the rejection of claims 7, 8, 19 and 20 under 35 USC § 103(a) as being unpatentable over Acker et al '774 in view of Castel '550 is improper and should be withdrawn.

### Claims 3 and 15

Claims 3 and 15 have been rejected under 35 USC § 103(a) as being unpatentable over U.S. Patent No. 6,508,774 (“Acker et al ‘774”) in view of U.S. Patent No. 6,719,694 (“Weng et al ‘694”). These rejections are respectfully traversed.

The discussion of Acker et al ‘774 above is incorporated in its entirety. It is noted that Acker et al ‘774 is not a valid reference against the present application.

Weng et al ‘694 discloses ultrasound transducers for imaging and therapy. The multiple elements of a transducer array 133 are passed through linear array 131 and focused on a particular point 132 (Figures 3 – 6). But Weng et al ‘694 does not show, disclose or suggest a plurality of ultrasound emitting elements, independently actuatable, whereby the ultrasound energy is focused at separate and distinct locations for each individual element, and whereby a lesion is formed in accordance with the elements that are selected to be actuated.

By contrast, claims 1 and 9, as amended, from which claims 3 and 15 depend, respectively, recite a plurality of ultrasound emitting elements, independently actuatable, whereby the ultrasound energy is focused at separate and distinct locations for each individual element, and whereby a lesion is formed in accordance with the elements that are selected to be actuated. Thus, Weng et al ‘694 does not show, disclose or suggest multiple essential elements of independent claims 1 and 9, as amended. Claims 3 and 15 depend from claims 1 and 9, respectively, and as such incorporate all of the subject matter of the claims from which they depend. In addition, claims 3 and 15 recite additional patentable subject matter. Thus, the rejection of claims 3 and 15 under 35 USC § 103(a) as being unpatentable over Acker et al ‘774 in view of Weng et al ‘694 is improper and should be withdrawn.

### **New claims**

Claims 28 – 34 are new and depend from claim 1, claims 35 – 40 are new and depend from claim 9, and claims 41 – 47 are new and depend from claim 21, and as such incorporate all of the subject matter of the claims from which they depend. In addition, claim 28 – 47 recite additional patentable subject matter. Because claims 1, 9 and 21 are not rejectable in view of any of the cited documents, and because of the additional patentable subject matter, it is respectfully

submitted that claims 28 – 47 are in condition for allowance, and notice to that effect is earnestly solicited.

Claims 48 – 95 all recite, or depend from claims that recite, a plurality of a plurality of ultrasound emitting elements that are selectively independently actuatable, that the ultrasound energy is focused at separate and distinct locations for each individual ultrasound element, whereby a lesion of selected size and configuration is formed in accordance with the ultrasound emitting elements selected to be actuated. As has been established above with respect to the cited documents and claims 1 – 27, the Office Action does not cite any valid references that show, disclose or suggest this subject matter. Thus, it is respectfully submitted that claims 48 – 95 are in condition for allowance, and notice to that effect is earnestly solicited.

## Summary

In view of the amendments and arguments presented, claims 1 – 95 should be allowable, this application should be in condition for allowance and a notice to that effect is earnestly solicited.

## Correspondence

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Respectfully Submitted,

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